I

110TH CONGRESS
2D SESSION

H. R. 7163

To amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of medical waste.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2008

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of medical waste.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Waste Management Act of 2008''.

SEC. 2. TRACKING AND DISPOSAL OF MEDICAL WASTE.

(a) DEFINITION OF MEDICAL WASTE.—Section 1004 of the Solid Waste Disposal Act (42 U.S.C. 6903) is

amended by striking paragraph (40) and inserting the following:

''(40)(A) Except as provided in subparagraph (C), the term 'medical waste' means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.

''(B) Such term includes each of the following types of solid waste:

''(i) Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

''(ii) Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy.

''(iii) Waste human blood and products of blood, including serum, plasma, and other blood components.

"(iv) Sharps (as such term is defined by the Secretary) that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades.

"(v) Contaminated carcasses, body parts, and bedding of animals that have been exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

"(vi) Wastes from surgery or autopsy that have been in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.

"(vii) Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that have been in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.

"(viii) Dialysis wastes that have been in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters,

disposable sheets, towels, gloves, aprons, and laboratory coats.

''(ix) Discarded medical equipment and parts that have been in contact with infectious agents.

''(x) Solid wastes that are likely to be contaminated with infectious agents because the wastes have been in contact with humans or animals that are quarantined to protect other humans or animals from communicable disease.''

''(C) Such term does not include any hazardous waste identified or listed under subtitle C or any household waste as defined in regulations under subtitle C.

''(D) Not later than the last day of the two-year period beginning on the date of enactment of the Medical Waste Management Act of 2008, the Administrator shall promulgate regulations listing types of medical waste.''.

(b) AMENDMENT OF SOLID WASTE DISPOSAL ACT.—The Solid Waste Disposal Act is amended by striking subtitle J (42 U.S.C. 6992 et seq.) and inserting the following:

"Subtitle J—Medical Waste Management Program

"SEC. 11001. MEDICAL WASTE MANAGEMENT PROGRAM.

''(a) IN GENERAL.—The Administrator shall conduct a medical waste management program for the purpose of protecting human health and the environment from medical waste.

''(b) COMPONENTS OF PROGRAM.—The program under subsection (a) shall provide for the following:

''(1) Tracking medical waste from any generator of such waste to any disposal facility that disposes of such waste, including a record keeping system for generators who dispose of medical waste at the same facility where the waste is generated.

''(2) A uniform manifest form prepared by the generator of any medical waste that accompanies the waste as it is being transported from a generator to a disposal facility.

''(3) Labeling and packaging requirements that—

''(A) foster safe handling of the waste;

''(B) protect the public from exposure to infectious disease; and

''(C) provide for the identification of the generator of the waste.

''(4) Storage requirements, including a requirement for segregation of the waste at the point of generation and during transportation.

''(5) Proper disposal of medical waste through appropriate methods of disposal that—

''(A) are approved by the Administrator; and

''(B) provide adequate protection for the environment and human health.

''(6) Monitoring of generators and transporters of medical waste and disposal facilities that dispose of medical waste for compliance with the program under this section.

''(7) A requirement that such generators, transporters, and disposal facilities provide adequate training to individuals who handle medical waste to ensure compliance with the program under this section.

''(8) A national plan for managing medical waste generated in States with a shortage of disposal facilities.

''(c) EXEMPTIONS.—

''(1) PROPERLY TREATED WASTE.—

''(A) IN GENERAL.—Subject to paragraph (4), the Administrator may make an exemption

from some or all of the requirements of the program under subsection (a) for medical waste treated in a method described under subparagraph (B).

''(B) METHODS OF TREATMENT.—For purposes of this paragraph, the Administrator shall promulgate regulations establishing minimum standards for methods of treating medical waste that significantly reduce the potential harm of such waste to the environment and to human health.

''(2) STORAGE REQUIREMENTS.—Subject to paragraph (4), the Administrator may make an exemption to the requirement under subsection (b)(4) that medical waste be segregated from other waste upon receipt of a petition for such an exemption from a generator, transporter, or disposal facility.

''(3) INDIVIDUALS.—

''(A) IN GENERAL.—Subject to subparagraph (B) and paragraph (4), the Administrator shall make an exemption from the program under subsection (a) for individuals who generate medical waste through personal use of medical or non-medical products outside of a medical facility, so long as the Administrator

ensures that such exemption does not endanger the environment or human health.

''(B) NO EXEMPTION FOR LARGE VOLUMES OF WASTE.—The Administrator may not make an exemption under subparagraph (A) for an individual who generates 50 pounds or more of medical waste in any calendar month.

''(4) PROTECTION OF THE ENVIRONMENT AND HUMAN HEALTH.—The Administrator may not make an exemption under this subsection unless the environment and human health can be adequately protected, as determined by the Administrator.

''(d) REGULATIONS.—

''(1) IN GENERAL.—Tor purposes of the program under this section, not later than the last day of the 12-month period beginning on the date of enactment of the Medical Waste Management Act of 2008, the Administrator shall promulgate regulations on tracking, labeling, packaging, storing, handling, monitoring, and disposing of medical waste.

''(2) VARIATION IN RULES.—The regulations under paragraph (1) may include different rules for different types of medical waste and for different types of medical waste generators.

"SEC. 11002. SPECIFIC REQUIREMENTS FOR GENERATORS, TRANSPORTERS, AND DISPOSAL FACILITIES.

''(a) SPECIFIC REQUIREMENTS FOR GENERATORS.—A generator of medical waste shall—

''(1) provide any transporter that is transporting medical waste from the generator to a disposal facility—

''(A) with a written assurance that the generator has complied with all labeling, packaging, and storage requirements under section 11001 with respect to such medical waste; and

''(B) with a properly completed manifest form for transporting such waste under section 11001(b)(2);

''(2) register with the Administrator; and

''(3) provide the Administrator with the name of all transporters used by the generator to transport medical waste.

''(b) SPECIFIC REQUIREMENTS FOR TRANSPORTERS.—A transporter of medical waste shall—

''(1) not accept medical waste from a generator without receiving a written assurance, with regard to such waste, that is described in subsection (a)(1)(A);

''(2) register with the Administrator; and

''(3) disclose to the Administrator the number and type of vehicles used by the transporter to

transport medical waste and the equipment and methods used to ensure segregation and handling of such waste in accordance with this subtitle.

''(c) SPECIFIC REQUIREMENTS FOR DISPOSAL FACILITIES.—An owner or operator of a disposal facility shall—

''(1) provide notice of the disposal of medical waste to the generator of that medical waste; and

''(2) register with the Administrator.

''(d) REGISTRATION.—The Administrator may set appropriate requirements for registration under this section and may collect reasonable registration fees from generators, transporters, and disposal facilities.

''(e) AVAILABILITY OF FEES.—Subject to appropriations, fees collected under this section shall remain available for use by the Administrator for purposes of the medical waste management program under this subtitle.

''SEC. 11003. INSPECTIONS.

''(a) REQUIREMENTS FOR ACCESS.—

''(1) IN GENERAL.—Upon request of any officer, employee, or representative of the Environmental Protection Agency duly designated by the Administrator, for purposes of developing or assisting in the development of any regulation or report under this subtitle or enforcing any provision of this

subtitle, any person who generates, stores, treats, transports, disposes of, or otherwise handles medical waste shall furnish information relating to such waste (including any manifest forms required under section 11001), conduct monitoring or testing, and permit such officer, employee, or representative at all reasonable times to have access to, and to copy, all records relating to such waste.

''(2) SPECIFIC ACTIVITIES AUTHORIZED.—To carry out inspections for purposes of the program under section 11001, officers, employees, or representatives described under paragraph (1) are authorized to—

''(A) enter at reasonable times any building, vehicle, equipment, container, or other item or place where medical waste is generated, stored, treated, disposed of, or transported;

''(B) conduct monitoring or testing relating to such waste;

''(C) inspect any such waste and any containers, labels, and documents relating to such waste; and

''(D) obtain from any person—

''(i) samples of such waste; and

"(ii) samples or copies of such containers, labels, and documents.

"(b) PROCEDURES.—

"(1) PROMPT INSPECTIONS.—Each inspection under this section shall be commenced and completed with reasonable promptness.

"(2) SAMPLES.—

"(A) IN GENERAL.—If an officer, employee, or representative described under subsection (a)(1) obtains any samples under subsection (a)(2)(C), prior to leaving the site of inspection the officer, employee, or representative shall give to the owner, operator, or agent in charge a receipt describing each sample obtained.

"(B) ANALYSIS.—If any analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge of the site from which such sample was taken.

"(c) AVAILABILITY TO PUBLIC.—The provisions of section 3007(b) of this Act shall apply to records, reports, and information obtained under this section in the same manner and to the same extent as such provisions apply

to records, reports, and information obtained under section 3007.

"SEC. 11004. ENFORCEMENT.

"(a) COMPLIANCE ORDERS.—

"(1) VIOLATIONS.—Whenever, on the basis of any information, the Administrator determines that any person has violated, or is in violation of, any provision of this subtitle (including any regulations promulgated to carry out this subtitle)—

"(A) the Administrator may issue an order—

"(i) assessing a civil penalty for such violation;

"(ii) requiring compliance with the provision being violated immediately or within a specified time; or

"(iii) both; or

"(B) the Administrator may commence a civil action in the United States district court in the district in which the violation occurred for appropriate relief, including a temporary or permanent injunction.

"(2) ORDERS ASSESSING PENALTIES.—

"(A) AMOUNT.—Any penalty assessed in an order under this subsection shall not exceed

$50,000 per day of noncompliance for each violation of a requirement or prohibition in effect under this subtitle.

''(B) CONSIDERATIONS FOR ASSESSMENT OF PENALTY.—In assessing such a penalty, the Administrator shall take into account the seriousness of the violation and any good faith efforts by the violator to comply with applicable requirements.

''(3) SPECIFICITY OF ORDERS.—Any order issued pursuant to this subsection shall state with reasonable specificity the nature of the violation.

''(4) FINALITY OF ORDER.—Any order issued under this subsection shall become final unless, not later than 30 days after issuance of the order, the persons named therein request a public hearing.

''(5) PUBLIC HEARING.—Upon request for a public hearing under paragraph (4), the Administrator shall promptly conduct the public hearing.

''(6) VIOLATION OF COMPLIANCE ORDERS.—In the case of an order under this subsection requiring compliance with any provision of or regulation promulgated to carry out this subtitle, if a violator fails to take corrective action within the time specified in the order, the Administrator may access a civil pen-

alty of not more than $50,000 for each day of continued noncompliance with the order.

"(b) CRIMINAL PENALTIES.—

"(1) IN GENERAL.—Whoever—

"(A) knowingly violates—

"(i) any provision of this subtitle; or

"(ii) regulations promulgated to carry out this subtitle;

"(B) knowingly omits material information or makes any false material statement or representation in any label, record, report, or other document filed, maintained, or used for purposes of compliance with this subtitle or regulations thereunder; or

"(C) knowingly generates, stores, treats, transports, disposes of, or otherwise handles any medical waste and who knowingly destroys, alters, conceals, or fails to file any record, report, or other document required to be maintained or filed for purposes of compliance with this subtitle or regulations thereunder;

shall be fined under title XVIII, United States Code, or imprisoned for a maximum of four years (ten years in the case of a violation of subparagraph

(A)), or both. Each day of a violation under this paragraph is a separate offense.

''(2) KNOWING ENDANGERMENT.—

''(A) IN GENERAL.—Any person who knowingly violates any provision of paragraph (1) and who knows at the time of such violation that, through such violation, another person is placed in imminent danger of death or serious bodily injury, shall be fined $350,000, or imprisoned for a maximum of 15 years, or both.

''(B) SPECIAL RULES.—The provisions of section 3008(f) of this Act shall apply to this subsection.

''(c) CIVIL PENALTIES.—

''(1) IN GENERAL.—Any person who violates any provision of this subtitle or regulation promulgated to carry out this subtitle shall be liable to the United States for a civil penalty in an amount not to exceed $50,000 for each such violation.

''(2) REPEAT VIOLATIONS.—For purposes of this subsection, each day of such violation shall constitute a separate violation.

''(3) POLICY.—Civil penalties assessed by the United States or by the States under this subtitle shall be assessed in accordance with the Administra-

tor's 'RCRA Civil Penalty Policy', as such policy may be amended from time to time.

''(d) SUBPOENAS.—In connection with any proceeding under this section, the Administrator may issue subpoenas for the production of relevant papers, books, and documents, and may promulgate rules for discovery procedures.

"SEC. 11005. RELATIONSHIP TO STATE LAW.

''(a) STATE INSPECTIONS AND ENFORCEMENT.—A State may conduct inspections under section 11003 and take enforcement actions under section 11004 against any person, including any person who has imported medical waste into a State in violation of the requirements of, or regulations under, this subtitle, to the same extent as the Administrator.

''(b) NOTIFICATION.—At the time a State initiates an enforcement action under section 11004 against any person, the State shall notify the Administrator in writing.

''(c) PREEMPTION.—This subtitle preempts the law of any State to the extent such laws are inconsistent with this subtitle, except that this subtitle shall not preempt any State law that provides additional protections for human health and the environment, as determined by the Administrator.

''(d) STATE FORMS.—Any State or local law which requires submission of a tracking form from any person subject to this subtitle shall require that the form be identical in content and format to the manifest form required under section 11001, except that a State may require the submission of other tracking information which is supplemental to the information required on such manifest form through additional sheets or such other means as the State deems appropriate.

''(e) RETENTION OF STATE AUTHORITY.—Except as provided in subsections (c) and (d), nothing in this subtitle shall affect any State or local law or the authority of any State or local government to adopt or enforce any State or local law.

''SEC. 11006. SYRINGE DISPOSAL PROGRAM.

''(a) IN GENERAL.—The Administrator shall establish a program on syringe disposal to—

''(1) educate the public about acceptable methods for disposal of used syringes generated by individuals through personal use of such syringes outside of medical facilities, including through household use; and

''(2) provide grants to State and local governments and nonprofit and private entities—

''(A) to educate the public about such methods; and

''(B) to increase access to such disposal methods.

''(b) ACCEPTABLE DISPOSAL METHODS.—For purposes of this section, acceptable methods of disposal of used syringes shall be determined by the Administrator and may include community drop-off programs, hazardous waste facilities that accept household waste, mail-back programs, syringe exchange programs, and needle destruction devices. Disposal in household garbage is not an acceptable disposal method.

''SEC. 11007. REPORTS TO CONGRESS.

''(a) ANNUAL REPORT.—

''(1) IN GENERAL.—Not later than one year after the date of enactment of the Medical Waste Management Act of 2008 and annually thereafter, the Administrator shall report to Congress on the following:

''(A) The types, number, and size of generators of medical waste in the United States.

''(B) The types and amounts of medical waste generated in the United States.

''(C) The methods currently used to handle, store, transport, treat, and dispose of the

medical waste, including the extent to which such waste is disposed of in sewer systems.

''(D) The present and potential costs—

''(i) to local economies, persons, and the environment from the improper handling, storage, transportation, treatment, or disposal of medical waste; and

''(ii) to generators, transporters, and treatment, storage, and disposal facilities from regulations establishing requirements related to tracking, handling, storing, transporting, treating, and disposing of medical waste.

''(E) Available and potentially available methods for handling, storing, transporting, and disposing of medical waste and their advantages and disadvantages.

''(F) Available and potentially available methods for treating medical waste, including methods of sterilization, chemical treatment, and grinding.

''(G) The advantages and disadvantages of such treatment methods, including the extent to which such methods—

"(i) render medical waste noninfectious or less infectious;

"(ii) make medical waste unrecognizable; and

"(iii) protect human health and the environment.

"(H) Factors impacting the effectiveness of the treatment methods identified in subparagraph (F), including quality control and quality assurance procedures, maintenance procedures, and operator training.

"(I) Available and potentially available methods for the reuse or reduction of the volume of medical waste generated.

"(J) The appropriateness of the penalties provided in section 11004 for insuring compliance with the requirements of this subtitle, including a review of the level of penalties imposed under this subtitle.

"(b) STUDY AND REPORT ON INDIVIDUAL GENERATORS.—

"(1) STUDY.—The Administrator shall conduct a study on—

"(A) the type of medical waste (including used syringes) generated by individuals through

personal use of medical products outside of medical facilities;

''(B) the volume of such waste;

''(C) the availability and cost of disposal and treatment of such waste;

''(D) the impact on the environment and human health of excluding such waste from the medical waste management program under section 11001; and

''(E) the extent to which individuals are aware of and use available disposal and treatment options for such waste.

''(2) REPORT.—Not later than the last day of the one-year period beginning on the date of enactment of the Medical Waste Management Act of 2008, the Administrator shall submit a report to Congress containing—

''(A) the results of the study under paragraph (1);

''(B) recommended standards for the handling, storage, treatment, and disposal of such waste; and

''(C) recommendations for educating the public about such standards.

''(c) CONSULTATION.—In preparing the reports under this section, the Administrator shall consult with appropriate State and local agencies.

''SEC. 11008. GENERAL PROVISIONS.

''(a) CONSULTATION.—(1) In promulgating regulations under this subtitle, the Administrator shall consult with the States and may consult with other interested parties.

''(2) The Administrator shall also consult with the International Joint Commission (as established by the Boundary Waters Treaty of 1909 between Canada and the United States) to determine how to track medical waste entering the United States from Canada.

''(b) PUBLIC COMMENT.—In the case of the regulations required by this subtitle to be promulgated within nine months after the date of enactment of the Medical Waste Management Act of 2008, the Administrator may promulgate such regulations in interim final form without prior opportunity for public comment, but the Administrator shall provide an opportunity for public comment on the interim final rule.

''(c) PAPERWORK REDUCTION ACT.—The promulgation of such regulations shall not be subject to the Paperwork Reduction Act of 1980.

''(d) RELATIONSHIP TO SUBTITLE C.—Nothing in this subtitle shall affect the authority of the Administrator to regulate medical waste under subtitle C of this Act.

''SEC. 11009. EFFECTIVE DATE OF REGULATIONS.

''The regulations promulgated under this subtitle shall take effect on the last day of the 90-day period beginning on the date such regulations are promulgated.''.

(c) TABLE OF CONTENTS.—The table of contents for the Solid Waste Disposal Act is amended by striking the items relating to subtitle J and inserting the following:

○